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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,327	09/28/1999	GEORGE H. LOWELL	406462000102	2613

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/407,327	LOWELL, GEORGE H.	
	Examin r	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,4,17 and 18* is/are allowed.

6)☒ Claim(s) *6-12 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *25* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 6-2-2003 are acknowledged. Claims 1, 6-12 and 16 have been amended. Claims 2-3, 5 and 13-15 have been canceled. Claims 17 and 18 have been added. Claims 1, 4, 6-12 and 16-18 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 6-2-2003 is acknowledged. An initialed copy is attached hereto.

Claim Rejections Withdrawn

The rejection of claims 1-4 and 13-15 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide and methods of achieving immunity using said vaccines/compositions, does not reasonably provide enablement for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier, nor does it enable methods of achieving immunity using said vaccines/compositions is withdrawn. Applicant's arguments with regard to claims 1 and 4 have been fully considered and deemed persuasive. The cancellation of claims 2-3 and 13-15 have rendered the rejection with regard to said claims moot.

The rejection of claim1 as being rendered vague and indefinite by the use of the term "an effective amount" is withdrawn in light of the amendment thereto.

The rejection of Claim 2 for having insufficient antecedent basis for the limitation "lipopolysaccharide" is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 2 as being rendered vague and indefinite by the use of the phrase "is from Shigella" is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 3 as being rendered vague and indefinite by reciting improper Markush language is withdrawn. Cancellation of said claim has rendered the rejection moot.

The rejection of claim 7 as being rendered vague and indefinite by the use of the phrase "providing enhanced immunogenicity" is withdrawn in light of the amendment thereto.

The rejection of claims 7 and 8 as being rendered vague and indefinite by the use of the phrases "impart enhanced immunity" and "impart immunity" is withdrawn in light of the amendment thereto.

The rejection of claims 8-16 as being rendered vague and indefinite by the use of the phrase "achieving immunity" is withdrawn in light of the amendment to claims 8-12 and 15 and the cancellation of claims 13-15.

The rejection of claims 1, 6-9 and 16 under 35 U.S.C. 102(a) as being anticipated by Livingston et al. (Vaccine Vol. 11, No.12, pages 1199-1204, 1993 – IDS-5) is withdrawn in light of the Declaration filed under 37 C.F.R. 1.132.

Claim Rejections Maintained and New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 6-12 and 16 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide and methods of achieving immunity using said vaccines/compositions, does not reasonably provide enablement for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier, nor does it enable methods of achieving immunity using said vaccines/compositions is maintained for the reasons set forth in the rejection of claims 1-4 and 6-16 in the previous Office action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or **use** the invention commensurate in scope with these claims.

Applicant argues:

1. The specification defines glycolipid as "a compound containing one or more monosaccharide residues bound by a glycosidic linkage to a hydrophobic moiety, such as an acylglycerol, a sphingoid, a ceramide or a prenyl phosphate."

2. Since the hydrophobic chains are very similar, it has been demonstrated that a vaccine that induces antibodies specific to the carbohydrate residue (gangliosides) is representative of the family of glycolipids.

3. Applicant has disclosed an example of a glycolipid, which is in the class of molecules claimed, and one of skill in the art would be able to substitute other glycolipids for the exemplified one and prepare and use said compositions.

4. The reference by Livingston et al. (Vaccine Vol. 11 No. 12, pages 1199-1204, 1993) demonstrates that Applicant has shown the effectiveness of a glycolipid/proteosomes vaccine.

Applicant's arguments have been fully considered and deemed non-persuasive. Based on the definition of "glycolipid" disclosed in the specification, said claims are drawn to compositions/vaccines that comprise a myriad of molecules in addition to gangliosides.

The rejected claims are drawn to the compositions/vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier and the **prophylactic use** of said compositions/vaccines. The rejected claims require that the claimed vaccines/compositions induce protective immunity (i.e. are prophylactic) not merely induce antibody production as asserted by Applicant (Point 1). To be a prophylactic composition, said composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed compositions/vaccines provide any sort of protective immunity in any model system that can be extrapolated to humans or other mammals. Additionally, Applicant has not demonstrated the efficacy of the

GD3/proteosomes composition as a **vaccine** against **any** type of infection or disease other than the complement lysis of tumor cells expressing GD3 (see page 1203 of Livingston et al.). Neither the specification, nor any of the references cited by Applicant, provide any guidance with regard to whether a given glycolipid in combination with proteosomes from a given bacterial species would have any efficacy as a vaccine against a given infection or disease. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier, nor does it enable methods of achieving immunity using said vaccines/compositions.

With regard to the disclosure by Livingston et al., said reference only illustrates the efficacy of a single species of glycolipid (GD3) to induce an immune response against a tumor antigen and as such is not commensurate in scope with the instant claims.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered vague and indefinite by the use of the phrase "inducing immunogenicity". It is unclear how the administration of a "composition" to a subject induces its immunogenicity since immunogenicity is an inherent property of said composition.

Conclusion

Claim 1, 4 and 17-18 are allowed.

Claims 6-12 and 16 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXA
TECHNOLOGY CENTER 1600

Robert A. Zeman
August 14, 2003